EUROPEAN STANDARDISATION OF SERVICES AND ITS IMPACT ON PRIVATE LAW

PARADOXES OF CONVERGENCE

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EUROPEAN STANDARDISATION OF HEALTHCARE SERVICES

After the analysis of the legal framework for European standardisation of services, this chapter will focus on European standardisation in the healthcare sector. In order to understand the potential of European standardisation of healthcare services to play a role in private law, the regulatory framework for healthcare services – both at the European and at the national level – has to be set out. The first part analyses the interaction between EU law and healthcare services. This will be done by looking at the impact of primary EU law, secondary EU law and European standardisation. The perspective then shifts to the national level to discuss what the role of private law is in the regulation of healthcare services, and to see what the potential impact of European standardisation could be. Finally, three case studies on European standardisation of services will be introduced. The chapter concludes with an analysis of the interaction between European standardisation and healthcare services.

I. THE INTERACTION BETWEEN EU LAW AND HEALTHCARE SERVICES

A. The lack of EU competence to regulate healthcare services

Healthcare is not one of the traditional competences of the EU. The healthcare systems of the various EU Member States are all very different in nature and are based on different cultural perceptions of how healthcare should be delivered and regulated. From a political point of view, it was considered undesirable for the EU to intervene in these national systems. The organisation of the healthcare systems was too closely linked to the national identity of the Member States, which strongly opposed any direct influence of the EU. Furthermore, healthcare services were traditionally local, in that patients would go to the general practitioner or hospital in their neighbourhood. Until relatively recently, the cross-border dimension which could possibly justify regulatory intervention by the EU was missing.

Despite the absence of an express legal basis to regulate healthcare services, there are various areas of EU law which have had an impact on healthcare systems. For example, the Working Time Directive[1] has had a profound impact on the organisation of healthcare at the national

[1] Council Directive 93/104/EC concerning certain aspects of the organization of working time.

level.[2] As a result, stakeholders in the healthcare sector are well aware of the possible impact of EU regulation on the delivery of healthcare services. Furthermore, various aspects of EU regulation touch on (public) health issues. From the 1970s onwards, several measures had been adopted which could be considered to have improvement of public health as (one of) their main aims. The legal bases of these measures were uncertain or disputed.[3] For that reason and for reasons of transparency, it was decided that the EU should be given a complementary competence in the field of public health. This competence was introduced by the Treaty of Maastricht. It provided that "the Community shall contribute towards a high level of human health protection by encouraging cooperation between Member States, and, if necessary, lending support to their action".[4] After the adoption of the Treaty of Lisbon, it is now expressly stated that the protection of a high level of human health is one of the areas in which the EU only has a complementary competence.[5] Harmonisation of legislation is expressly excluded. Wolf Sauter has argued that this express recognition makes it clear that the EU intends to comply with the principle of subsidiarity and that it is recognised that this is an area of national competence.[6] The complementary competence itself is now found in Article 168 TFEU. First of all, it provides that "a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities".[7] As to the substance of the competence, the provision is now significantly more detailed than before. Article 168(1) provides that "Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health". This is then followed by some examples of possible action by the Union. In addition to this, Article 168(2) provides that the EU shall encourage cooperation between the Member States on these issues.

From the late 1990s and early 2000s, various cases have reached the CJEU which dealt with the possibility of reimbursement for patients of the costs of healthcare services which they had received in another Member State.[8] The impact of these cases will be discussed below. Most

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[2] Interview with UEMS and CPME (Warsaw) on 19 February 2013.
[3] T Hervey, 'Community and National Competences in Health after *Tobacco Advertising*' (2001) 38 *CML Rev* 1421, 1422.
[4] Article 129 EC, introduced by the Treaty of Maastricht.
[5] Article 6(a) TFEU, introduced by the Treaty of Lisbon.
[6] W Sauter, 'Harmonisation in healthcare: the EU patients' rights Directive' (2011)*TILEC Research Paper* 6, 3.
[7] Article 168(1) TFEU.
[8] In particular, see Case C-120/95, *Decker v Caisse de maladie des employés privés*, ECLI:EU:C:1998:167; Case C-158/96, *Kohll v Union des caisses de maladie*, ECLI:EU:C:1998:171; Case C-368/98, *Vanbraekel and others v Alliance nationale des mutualités chrétiennes*, ECLI:EU:C:2001:400; Case C-157/99, *Geraets-Smits v Stichting Ziekenfonds* and *Peerbooms v Stichting CZ Groep Zorgverzekeringen*, ECLI:EU:C:2001:404; Case C-385/99, *Müller-Fauré v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* and *van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen*, ECLI:EU:C:2003:270; Case C-

cases were brought on the basis of the right of service recipients to freely receive services in another Member State. The CJEU decided that healthcare services were not excluded from the scope of application of the right to free movement of services. Therefore, in theory, it became possible for the EU to adopt legislation on the basis of its internal market competence. However, the relationship between the internal market competence and the complementary competence in health was uncertain. The extent to which the internal market competence would provide an adequate and correct legal basis for harmonisation of healthcare services was debated.[9] This debate was well illustrated by the opposition to the inclusion of healthcare services in the Services Directive.[10] In the end, it was decided that healthcare services required a special solution. This solution came with the adoption of the Cross-Border Healthcare Directive in 2011.[11] The adoption of the Directive was based both on Article 114 TFEU – the internal market competence – and Article 168 TFEU. The focus of this Directive is on the reimbursement of healthcare services which have been received outside a patient's home Member State. As such, it remains very close to the CJEU's case law and could be regarded as codification of its case law.[12] However, the Directive goes further in that it also includes a number of information rights which are granted to patients who receive healthcare abroad. This means that the EU has chosen to complement the reimbursement rights with a number of traditional consumer rights. The cross-border patient is also considered to be a consumer. This is in line with the arguments of Gareth Davies, who has argued that it would be preferable to realise changes in national healthcare systems through granting individual private law rights to patients rather than through harmonising at the European level aspects of the delivery of healthcare services.[13] Such a consumer-based approach would rely on the individual to challenge obstacles encountered in national healthcare systems and, through individual litigation, to bring about a more outward-looking perspective of national healthcare systems.

Overall, the fact remains that the EU has not intervened in the standards or the quality of healthcare provided to patients at the national level. The Cross-Border Healthcare Directive provides that high-quality treatment shall be provided, but the meaning of high-quality is not

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56/01, *Inizan v Caisse primaire d'assurance maladie des Hauts-de-Seine*, ECLI:EU:C:2003:578 and Case C-372/04, *The Queen ex parte Watts v Bedford Primary Care Trust and Secretary of State for Health*, ECLI:EU:C:2006:325.

[9] D Wyatt, 'Community Competence to Regulate Medical Services' in M Dougan and E Spaventa (eds), *Social Welfare and EU Law* (Oxford, Hart Publishing, 2005), 131-144.

[10] Interview with UEMS and CPME (Warsaw) on 19 February 2013.

[11] Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare.

[12] S de la Rosa, 'The Directive on Cross-Border Healthcare or the Art of Codifying Complex Case Law' (2012) 49 *CML Rev* 15.

[13] G Davies, 'The Community's Internal Market-Based Competence to Regulate Healthcare: Scope, Strategies and Consequences' (2007) 14 *Maastricht J. Eur. & Comp. L.* 215.

further defined in the Directive. There is also a reference to good quality healthcare in the Directive.[14] It is difficult to interpret these standards as autonomous European standards, since it is expressly provided in the Directive that the standards of care remain national.[15] This is important from the perspective of convergence. While Member States will be required to reimburse healthcare received in another Member State, they have to do so on the basis of the treatment which would have been provided in the home Member State.[16] One could wonder to what extent such reimbursement leads to mutual recognition. This is an interesting question, perhaps more of theoretical than of practical importance, which has not been discussed in the literature. Member States have to compensate patients for treatment in another Member State, but only up to the level which the patient would have received if he had stayed at home. This arrangement does not imply any mutual recognition of the regulatory choices made by the other Member States – the national treatment remains the basis of compensation. It would have been different if the Member States had to reimburse the full rate of treatment – whatever the costs of the treatment in the other Member State. Furthermore, reimbursement does not necessarily imply that the regulatory standards are similar.

The question then remains whether the EU would be able to harmonise standards of healthcare on the basis of its internal market competence. Derrick Wyatt has argued that the EU could circumvent the presumed lack of legal competence through the internal market competence.[17] This would allow the EU to adopt measures which could remove obstacles to free movement or distortions of competition. The various differences in the standards and quality of healthcare services in the 28 Member States could amount to an obstacle to the free movement of healthcare service recipients. Wyatt realistically accepts that "the proposition that lack of consumer confidence in the minimum guaranteed standards for the supply of goods and services in other Member States should be regarded in itself justifying harmonisation is one of which the present author is sceptical".[18] However, at the same time, he argues that "different standards of care resulting from disparities between national rules or administrative action in the various Member States could lead to distortion in the conditions of competition".[19] This argument appears to be quite formalistic from a legal point of view. Furthermore, it does not face up to the political reality that Member States do not want to limit their own sovereignty in the healthcare sector. Overall, it can be concluded that the EU internal market competence is unlikely to be

[14] Recital 64 and Article 4(1) of the Cross-Border Healthcare Directive (which refers to "good quality healthcare").
[15] Article 4(1)(b) of the Cross-Border Healthcare Directive.
[16] Article 7(1) of the Cross-Border Healthcare Directive.
[17] D Wyatt, above n 9, 136-138.
[18] Ibid., 141.
[19] Ibid., 141.

used to harmonise the standards of healthcare provided at the national level. The decision to argue that the internal market competence is sufficient to start harmonising the delivery of healthcare services is highly political and unlikely to be made in the near future. However, this does not mean that internal market law cannot have an indirect impact on the way in which national healthcare systems are regulated.

B. The impact of the case law on free movement of services on the regulation of healthcare services

From *Kohl*[20] and *Decker*[21], the CJEU has been forced to discuss a number of cases in which patients wanted to move across national borders to receive healthcare services. In general, the distinctive nature of these cases, which distinguished them from cases brought under the Social Security Regulation,[22] was that the sole purpose of the cross-border movement was to receive healthcare services in another Member State. The CJEU included the right to receive healthcare services within the scope of the free movement of services, which is now found in Article 56 TFEU.[23] The CJEU's case law has been extensively discussed elsewhere and it is not necessary to repeat these discussions in this section.[24] However, from the specific perspective of convergence, it is interesting to note the extent to which the case law has had a convergent effect on the national regulation of healthcare services. Therefore, a number of areas will be discussed on which the CJEU's case law has had a particular impact.

(i) Procedural requirements for prior authorisation of healthcare abroad

On the basis of the case law it is, in principle, possible for Member States to impose a system of prior authorisation for patients who seek hospital treatment in another Member State, if the treatment requires hospitalisation.[25] This could have an impact on private law, if patients have to obtain prior authorisation from the health insurer with which they hold their

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[20] Case C-158/96, *Kohll v Union des caisses de maladie*, ECLI:EU:C:1998:171.
[21] Case C-120/95, *Decker v Caisse de maladie des employés privés*, ECLI:EU:C:1998:167.
[22] Regulation (EC) No 883/2004 of the European Parliament and of the Council on the coordination of social security systems.
[23] Article 56 TFEU provides that restrictions to the right to provide services shall be restricted. This includes the right to receive services in another Member State: Joined Cases C-286/82 and C-26/83, *Luisi and Carbone,* ECLI:EU:C:1984:35.
[24] For a recent discussion, see J Baquero-Cruz, 'The Case Law of the European Court of Justice on the Mobility of Patients' in F Benyon (ed), *Services and the EU Citizen* (Oxford, Hart Publishing, 2013), 87-112. See also, in the same volume, R Cisotta, 'Limits to Rights to Health Care and the Extent of Member States' Discretion to Decide on the Parameters of Their Public Health Polices', 113-163.
[25] Case C-157/99, *Geraets-Smits v Stichting Ziekenfonds* and *Peerbooms v Stichting CZ Groep Zorgverzekeringen*, ECLI:EU:C:2001:404; Case C-385/99, *Müller-Fauré v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* and *van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* , ECLI:EU:C:2003:270.

insurance policy. The exact definition of hospitalisation was never provided by the CJEU, but it was clear that prior authorisation of non-hospital care would never be permissible. Furthermore, the CJEU has made it clear that Member States must have transparent procedures for cases in which authorisation can be required. Decisions of the decision-making body must be open to judicial review or some sort of quasi-judicial review proceedings, and they must be taken within a reasonable time-frame.[26]

(ii) Substantive requirements for prior authorisation of healthcare abroad

As a result of the case law of the CJEU, the substantive criteria which Member States use in deciding whether or not to authorise treatment in another Member State have become more converged. The CJEU held in *Geraets-Smits and Peerbooms* that the Dutch criterion of whether a treatment was "normal in the professional circles concerned" had to be interpreted from an international perspective – treatment sufficiently tried and tested by international science.[27] Relevant (international) scientific literature had to be taken into account. This means that Member States, in dealing with requests for prior authorisation, must look at treatments from an international point of view. They are not allowed to focus solely on national medical practice if this is unduly restrictive. The consequence is that the pallet of treatment options available to patients becomes broader and has to be interpreted from an international (and possibly European) perspective. This means that for out-going patients Member States are required to look at possible treatments in other Member States.

Secondly, in *Geraets-Smits and Peerbooms*, the criterion that treatment abroad was a medical necessity - which in practice meant that the treatment could not be offered without undue delay in the home Member State – was justified as long as the decision-making body took all the specific circumstances of the case into account.[28] Consequently, Member States are no longer justified in referring to the acceptable lengths of national waiting lists as an outright justification to refuse authorisation to receive healthcare abroad. They must always make an individual assessment based on the current and individual circumstances of the patient.

The result of these substantive criteria for prior authorisation is that Member States are obliged to make an individual assessment of patients who would like to receive medical treatment abroad and that Member States are obliged to take international medical practice into account. This implies that Member States – at least at the level of prior authorisation –

[26] *Geraets-Smits* and *Peerbooms*, above n 25, para 90.
[27] Ibid, paras 97-98.
[28] Ibid, para 104.

can no longer close their eyes to medical practice in other Member States. It also applies to courts when they review decisions to refuse prior authorisation to patients who would like to receive healthcare services abroad.

(iii) Waiting lists

The individual assessment of the undue delay criterion (or medical necessity) has also had an impact on how Member States manage their waiting lists. It is no longer appropriate to refuse treatment abroad on the basis that the length of the waiting lists is acceptable. Each case requires an individual assessment of the circumstances of the patient.[29] This has obliged Member States to introduce a certain flexibility in their management of waiting lists, and where necessary to pro-actively seek cross-border treatment options. *Watts* is a very clear example of the impact of EU free movement law on the management of waiting lists.[30] The result of that case is that the UK's National Health Service ("NHS") now regularly sends patients to other Member States for treatment.[31]

(iv) Transparency of costs of treatment

Finally, the fact that non-hospital care has to be reimbursed and that prior authorisation can never be justified for those cases means that healthcare systems such as the NHS have to make the costs of the specific treatments transparent. Otherwise, it would be difficult or impossible to know to what extent treatment abroad will be reimbursed. The result is that Member States must make the costs of treatments accessible to patients. This is the case even if patients normally never see the prices of treatments, since they receive healthcare without having to pay for it.[32]

Overall, the case law has mainly focussed on the proceduralisation of the right of patients to receive healthcare abroad. However, there is one procedural area which might result in substantive convergence. This is the result of the judgment in *Geraets-Smits*. Member States must take international science into account in deciding whether or not to grant prior authorisation. As a result, an obligation is imposed on Member States to analyse international scientific evidence that is available in a particular field and to assess to what extent the national healthcare

[29] Case C-372/04, *The Queen ex parte Watts v Bedford Primary Care Trust and Secretary of State for Health*, ECLI:EU:C:2006:325, paras 119-120.
[30] Ibid.
[31] J Montgomery, 'Impact of European Union Law on English Healthcare Law', in M Dougan and E Spaventa (eds), *Social Welfare and EU Law* (Oxford, Hart Publishing, 2005), 145-156, 154.
[32] Ibid, 154-155.

system is able to provide healthcare services in accordance with this international evidence.[33] It is an implicit recognition that research in medicine has become significantly internationalised.[34] However, in practice, it has proved difficult for patients to base their claims on international scientific evidence, primarily because Member States retain a degree of discretion in deciding to what extent such international science is evidence-based.[35] Nevertheless, the result of such an evaluation could be that a Member State has to reimburse treatment which is not available in the home Member State, but which could be brought in a broader category of treatments that are compensated by the home Member State. That is what happened in *Elchinov*.[36] In effect, the CJEU imposed a duty of consistent interpretation on national courts – if it is at all possible to bring a foreign treatment within a category of treatments that are reimbursed in the home Member State, the national court should do so.[37] Although no reference was made to fundamental rights, the aim of this approach is to provide substance to the right of patients to have access to healthcare.[38] However, the danger is that it could encourage Member States to restrict the list of treatments at the national level by providing a very clear, but also very restrictive list with treatments available at the national level. This could become a particular problem for patients in the new Member States.[39] If Member States were to adopt such an approach, this could be in breach of the requirement of high-quality or good quality healthcare which is imposed by the Cross-Border Healthcare Directive 2011. In *Stamatelaki*,[40] the CJEU held that private healthcare received in another Member State cannot simply be excluded from reimbursement on the basis of its private nature, when private healthcare is not reimbursed in the home Member State. As a consequence, Member States are required to look at the substance of the treatment – not the status of its provider.

Finally, one can wonder to what extent the case law has had an impact on private law and on the possibility of convergence in private law. Here, it should be noted that this impact is very much dependent on how healthcare services are regulated at the national level. However, in general, the series of free movement cases has had a limited impact on private law relations. Because of

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[33] A den Exter, 'Health Care Access in the Netherlands: a True Story', in C Flood and A Gross (eds), *The Right to Health at the Public/Private Divide* (Cambridge, CUP, 2014), 188-207, 200. See also G Davies, 'Legislating for Patients' Rights' in J. van der Gronden et al. (eds), *Health Care and EU Law* (The Hague, Asser, 2011), 191-210, 204.
[34] N Cortez, 'International Health Care Convergence: The Benefits and Burdens of Market-Driven Standardization' (2008) 26 *Wisconsin International Law Journal* 646.
[35] A den Exter, above n 33, 200-201.
[36] Case C-173/09, *Elchinov* v. *Natsionalna zdravnoosiguritelna kasa*, ECLI:EU:C:2010:581.
[37] Ibid, paras 68-73.
[38] Expressly recognised in the Bulgarian legislation referred to in the judgment, see para.7.
[39] T Sokol, 'Rindal and Elchinov: A(n) (Impending) Revolution in EU law on Patient Mobility?' (2010) 6 *Croatian Yearbook of European Law and Policy* 167.
[40] Case C-444/05, *Stamatelaki v NPDD Organismos Asfaliseos Eleftheron Epangelmation*, ECLI:EU:C:2007:231.

the focus on reimbursement and prior authorisation, the cases have intervened in the relationship between patient and the body which is responsible for reimbursing healthcare services. In most Member States, this is a public law relationship. In some Member States, such as the Netherlands, the case law has had an impact on the relationship between health insurer and patient, which would in principle be a private law relationship. However, health insurers operate in a regulatory framework which is strictly controlled and regulated by public law. Although the case law has an impact on the contractual relationship between insurer and patient, the content of the contract has to a significant extent been decided by public bodies. Despite this limited effect on the relationship between insurer and patient, it is clear that the case law has not had an impact on the private law relationship between doctor and patient – whether this relationship is considered to be contractual or in tort. All the cases have dealt with the rights of patients vis-à-vis the body that is responsible for paying for healthcare services. The case law under Article 56 TFEU has not had an effect on what patients can claim from their doctor. The next step is then to analyse to what extent the Cross-Border Healthcare Directive 2011 will go beyond the case law on the free movement of services.

C. The impact of the Cross-Border Healthcare Directive 2011 on the regulation of healthcare services

It is generally agreed that the adoption of the Cross-Border Healthcare Directive was primarily a codification exercise.[41] The Directive codifies the CJEU's case law on the free movement of patients. The articles on reimbursement of healthcare received in another Member State from the one in which the patient is affiliated to the healthcare system closely follow the rules laid down by the CJEU.[42] The same is true for the rules on prior authorisation. The situations in which cross-border healthcare can be subject to prior authorisation are exhaustively listed.[43] They include hospital treatment. However, an interesting difference – or clarification – with the case law is that the definition of hospital treatment which can be subject to prior authorisation is healthcare which involves overnight accommodation in hospital.[44] As a consequence, it appears that out-patient treatment in hospital can no longer be subject to prior authorisation.

In a number of areas, the Directive goes further than the case law. As such, it attempts to realise convergence of national healthcare regulation through harmonisation in a limited number of areas. The competence on which these harmonisation aspects are based is the same as that of the

[41] S de la Rosa, above n 12.
[42] Ibid, and see also W Sauter, above n 6.
[43] Article 8(2) of the Cross-Border Healthcare Directive.
[44] Article 8(2)(a)(i) of the Cross-Border Healthcare Directive.

overall Directive – the competence to regulate the internal market.[45] It should be noted that the Directive was adopted in early 2011 and that the deadline for transposition in national law was 25 October 2013. Therefore, the actual effect of the Directive in practice is still difficult to measure. However, it is clear there are significant differences in how and to what extent Member States have implemented the Directive.[46] These difficulties can be explained by some of the new concepts introduced in the Directive and the need for Member States to adapt the requirements of the Directive to their national health systems. There are a number of areas where the Directive adds something to the case law of the CJEU.

(i) Quality standards

The Directive obliges Member States to provide cross-border healthcare in accordance with standards and guidelines laid down by the Member State of treatment.[47] This does not directly encourage any convergence of standards, let alone the creation of European standards, but it does mean that Member States must have standards in place. Member States that have insufficient or no quality standards will be required to adopt such standards for the purpose of cross-border healthcare. If national standards are not available, Member States could decide to adopt international or European standards. It is unlikely that the effect of these standards would be limited to healthcare provided to patients coming from other Member States. Article 4(1) of the Directive also provides that Member States must take the principles of universality, access to good quality care, equity and solidarity into account in providing cross-border healthcare.[48] This could mean that Member States are required to provide healthcare of a certain minimum quality level, and could even be required in certain circumstances to amend their quality standards to provide healthcare of a higher standard.

(ii) Accessibility of quality standards

In addition to having standards in place, these standards must also be accessible to patients from other Member States.[49] Member States must establish information points which can provide patients in other Member States with relevant information on the standards and guidelines which are in place in the Member State of treatment.

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[45] Recital 2 of the Cross-Border Healthcare Directive.
[46] H Nys, 'The Transposition of the Directive on Patients' Rights in Cross-Border Healthcare in National Law by the Member States: Still a Lot of Effort to Be Made and Questions to Be Answered' (2014) 21 *European Journal of Health Law* 1. See also D Goscinska, 'Transposition of the Patients' Rights Directive 2011/24/EU: A Discourse Analysis in Germany, Poland and Austria', *Working Papers in Health Policy and Management*, Volume 8, TU Berlin, February 2014.
[47] Article 4(1)(b) of the Cross-Border Healthcare Directive.
[48] Article 4(1) of the Cross-Border Healthcare Directive.
[49] Article 4(2)(a) of the Cross-Border Healthcare Directive.

(iii) Information requirements

The Directive goes quite far in the information requirements that are imposed on healthcare providers. Article 4(2)(b) obliges healthcare providers to help patients to make an informed choice.[50] This includes information on:

(a) Treatment options
(b) Availability of healthcare
(c) Quality and safety of healthcare
(d) Prices and invoices
(e) Registration status and insurance of healthcare professionals

These criteria all go some way towards providing a basis for informed consent. Consequently, the Directive protects patients who are considering cross-border healthcare by granting them a number of information rights. As such, the protection focusses on the service recipient – the patient in this case – and aims as much as possible to make the patient a well-informed consumer.[51] In principle, these requirements are imposed on healthcare providers in the context of cross-border healthcare. However, the practical effect is that domestic patients will also receive this information. It is unlikely that Member States will create different information obligations depending on the origin of the patient. Such a distinction could realistically only be made in respect of language requirements. In this way, the Directive might also improve the provision of information to patients who remain within their home Member State.[52]

(iv) Complaints and insurance

Finally, the 2011 Directive obliges Member States to have transparent complaints mechanisms in place for patients.[53] Furthermore, the Member State is required to have a system of professional liability insurance in place.[54]

Unlike the case law of the CJEU, the Directive seems to have a direct impact on the patient-doctor relationship. This would mainly be through the information requirements. However, it is

[50] Article 4(2)(b) of the Cross-Border Healthcare Directive.
[51] In line with the arguments of G Davies, above n 13.
[52] D Delnoij and W Sauter, 'Patient information under the EU's patients' rights Directive' (2011) 21 *European Journal of Public Health* 271. See also W Palm and R Baeten, 'The quality and safety paradox in the patients' rights Directive' (2011) 21 *European Journal of Public Health* 272.
[53] Article 4(2)(c) of the Cross-Border Healthcare Directive. The standards for these procedures could be based on Commission Recommendation 98/257/EC on the out-of-court settlement of consumer disputes.
[54] Article 4(2)(d) of the Cross-Border Healthcare Directive.

clear from the wording and the structure of the Directive that the obligations are imposed on the Member States, and not directly on healthcare providers. It seems very unlikely that the obligations in Article 4 would have direct effect in a dispute between a healthcare provider and a patient. Nevertheless, it is clear that by granting a number of consumer-like rights, the Cross-Border Healthcare Directive has more of an impact on the private law aspects of the patient-doctor relationship. However, its main focus is still procedural rather than substantive. This opens up the possibility for European standardisation to intervene directly in the patient-doctor relationship by regulating substantive aspects of the patient's treatment.

D. The role of European standardisation in the regulation of healthcare services

On the basis of the discussion above, it is clear that both the case law on the free movement of patients and the Cross-Border Healthcare Directive have realised some convergence in the regulation of healthcare services in the Member States. The Directive has codified the case law, but has also imposed a number of additional information obligations. This means that the standards of care become more accessible and transparent. However, because of the EU's lack of legal competence to regulate quality of healthcare directly, both the case law and the Directive are still based on the presumption that the standards for healthcare services are defined at the national level. They do not directly interfere with the national definition of quality of care. Member States are merely encouraged to exchange national standards.

In a European internal market for healthcare services, such an exchange could eventually result in a need for a European definition of quality of care. This could be in areas in which there is a significant amount of cross-border movement of patients, or in areas in which the regulation of (private) healthcare services is very different in the various Member States. Member States are allowed under certain conditions to refuse prior authorisation of healthcare abroad.[55] One of them is Article 8(6)(c) of the Cross-Border Healthcare Directive, which provides that concerns about the quality of the healthcare providers are one of the legitimate reasons to refuse prior authorisation.[56] Again, therefore, there is an incentive in the Directive for quality to be regulated at the European level.

In this broader framework, standardisation would then become one of the options to regulate quality of care issues at the European level. European standardisation would intervene directly in the patient-doctor relationship by regulating aspects of the treatment. The standards in a European standard could be used directly in contractual disputes between healthcare providers

[55] Article 8(6) of the Cross-Border Healthcare Directive.
[56] Article 8(6)(c) of the Cross-Border Healthcare Directive.

and patients, or as a benchmark to determine the standard of care in contract or tort cases. A European standard would provide substantive rights as a supplement to the procedural rights provided in the Directive.

The next step is to see in which areas European standardisation processes have been started and what the underlying reasons for these processes were. However, before this can be done, it is necessary to describe in more detail how healthcare services are regulated at the national level, how public law and private law interact in the regulation of healthcare services and how European standardisation would fit in the national regulatory frameworks for healthcare services.

II. THE REGULATION OF HEALTHCARE SERVICES AT THE NATIONAL LEVEL AND THE ROLE OF PRIVATE LAW

A. The transformation of the character of healthcare services

This section will outline two developments that have taken place in the healthcare sector in the last few decades. The first has been on the macro level and has affected the way in which Member States have organised the delivery of healthcare services at the national level. The second development, which has partly been caused by the first development, has taken place at the level of the relationship between doctor and patient.

Traditionally, healthcare services have been strictly public and have been organised exclusively by the State. It was considered to be the ultimate responsibility of the State to ensure that its citizens would receive proper healthcare. This position has not really changed, but what we can see in the last decades is that Member States have introduced elements of competition and privatisation in their healthcare systems.[57] The result is that the public law character of the healthcare sector has diminished. One of the contributing factors to this development has been the project of the EU to liberalise services of public interest. Although this project has not had a direct impact on healthcare, it is clear that it has encouraged Member States to transform the healthcare sector in such a way that it also incorporates elements of competition.[58] This creation of a market for healthcare services also means that several provisions of EU law – such as competition law and free movement law – become applicable to the healthcare sector. The extent to which these market elements have been introduced differs among the Member States. What they have in

[57] M Krajewski, 'Healthcare Liberalisation in the EU and the WTO', in C Joerges and J Falke (eds), *Globalisation and the Potential of Law in Transnational Markets* (Oxford, Hart Publishing, 2011), 243. See also T Hervey, 'If Only It Were So Simple: Public Health Services and EU Law' in M Cremona (ed), *Market Integration and Public Services in the European Union* (Oxford, OUP, 2011), 179-250.
[58] T Hervey, above n 57, 209-214.

common in a significant number of Member States is that the bodies which – under public legislation – have been given responsibility to ensure the provision of healthcare services to their citizens or customers have to encourage competition among healthcare providers. They have a choice where to buy healthcare services, which means that healthcare providers have to compete for patients. The tool which is commonly used is a private law tool – contracts are concluded between healthcare "buyers" and healthcare providers. This has introduced market dynamics in the healthcare sector, in that healthcare providers become more focussed on profit-making.[59] Furthermore, public and private healthcare providers will more frequently compete for the provision of healthcare services. It is no longer guaranteed that contracts will go to public hospitals. As such, private healthcare has been given a more significant role in the healthcare system. The scope of private healthcare providers has been broadened. In addition to this, it has become more common for patients to seek private healthcare. The existence of private healthcare providers who provide supplementary services in addition to the public healthcare system means that patient choice is enhanced. Furthermore, for private healthcare which has been sought outside the public healthcare system, the relationship between patient and healthcare provider is contractual. Again, this means that private law will have more of an impact on the regulation of healthcare services. Moreover, the significant increase of private healthcare providers means that it is necessary for supervisory agencies to expand their work to the private sector. Often, it is difficult for them to get a full picture of what is going on in the private sector.[60] In general, both the limited liberalisation and privatisation have had an impact on the regulation of healthcare regulation and have created more of a role for private law, or quasi-private law, in the regulation of healthcare services.

The liberalisation and privatisation of healthcare services have not just had an impact on how the healthcare sector is organised. They have also had an impact on the relationship between doctor and patient. Just like the bodies that are responsible for buying healthcare services have been given more choice, patients have also been given more choice – even within the public healthcare systems of the Member States. Historically, patients go to local hospitals to see a doctor. Healthcare has a strong territorial element. This is not surprising – patients do not want to travel long distances for medical care, they like to build up a relationship with their doctor and

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[59] V Hatzopoulos, 'Health Law and Policy: The Impact of the EU', in G de Burca (ed), *EU Law and the Welfare State: In Search of Solidarity* (Oxford, OUP, 2005), 111-168. See also O Odudu, 'Are State-owned healthcare providers subject to competition law?' (2011) 32 *European Competition Law Review* 231 and H Schweitzer, 'Wettbewerb im Gesundheitswesen – rechtliche Grundlagen and rechtspolitische Grundfragen', in U Immenga and T Körber (eds), *Wettbewerb im Gesundheitswesen* (Baden-Baden, Nomos, 2013), 35-72.

[60] Interview with Chairman of Dutch Mirror Committee for Aesthetic Surgery Services (Goes) on 29 December 2012.

they prefer to have quick access to medical care. This local, territorial element of healthcare has not disappeared. However, the various developments in the healthcare sector have resulted in a new "type" of patient. This process could be described as the "consumerisation" of the patient.[61] The consumerisation of patients means that patients are becoming more and more like consumers. This implies an element of choice, and an element of "shopping for healthcare". This choice is granted by the co-existence of public and private healthcare providers and, as has already been said, by the possibility of choice within the public healthcare system. It can no longer be assumed that patients will go to the hospital next door – if there is a hospital a few hours away that offers specialist care of a higher quality, they will often opt for that hospital. This means that healthcare services are, to a certain extent, being removed from their territorial basis. Furthermore, patients have more access to information about the contents, the risks and the consequences of medical treatment. The number of internet fora and patient websites with medical information has increased enormously in the last couple of years – sometimes to the detriment of the accuracy of the information. The result of the increase in information is that patients have become more demanding towards doctors and will not hesitate to ask for a second opinion if they are not pleased with the diagnosis or proposal for treatment. Again, this could mean that patients will travel some distance to obtain a second opinion. Cross-border healthcare becomes a more realistic option. This consumerisation of the patient is also reflected in the Cross-Border Healthcare Directive itself. In addition to the right to reimbursement of cross-border healthcare, the focus of the Directive is very much on ensuring that patients are provided with adequate information.[62]

B. The interaction between public law and private law in the regulation of healthcare services at the national level

Because of its public nature, it is not surprising that healthcare is heavily regulated by public law at the national level. This section is not intended to provide a detailed overview of the legal regulation of healthcare services and providers at the national level. It will not engage in a detailed discussion of national systems. Rather, it will sketch out the landscape of public law and private law interaction in the healthcare sector in general. Inevitably, this means that certain generalisations are made about national healthcare systems, which are usually highly specific. The same applies to the legal regulation of national healthcare systems. However, this abstract picture of the landscape will provide an idea of the issues that are relevant to the ability of European

[61] See M Hall and C Schneider, 'Patients as Consumers: Courts, Contracts, and the New Medical Marketplace' (2008) 106 *Michigan Law Review* 643.
[62] W Sauter, above n 6.

standardisation to have an impact on the healthcare sector at the national level. The focus is on the interaction between public law and private law in the regulation of healthcare services and providers. Moreover, a distinction will be made between *ex ante* and *ex post* regulation.

Healthcare services would not be provided without medical professionals. Medical professionals need certain qualifications before they are allowed to practise medicine. The training requirements for doctors – as well as a number of other medical professionals – have been harmonised at the European level.[63] This has enabled the EU to adopt the Professional Qualifications Directive,[64] which provides that doctors who are qualified in one Member State should be allowed to offer their services in another Member States and should be admitted to the profession if they want to practise in another Member State on a permanent basis. It should be noted that this harmonisation has primarily been of a quantitative nature – recognition is based on the number of years of training. This is clear from the Directive itself.[65] The quantitative aspect of the harmonisation is supplemented with a more qualitative description of the substance of the training of medical practitioners. For medical specialists, the Union Européenne de Médicins Spécialists ("UEMS") is responsible for making the syllabi which contain the requirements for training for medical specialists.[66] This involves the bringing together of medical specialists of all Member States to decide on the required standards. As such, UEMS is essentially engaged in a form of standardisation. All of this takes place at the European level. At the national level, access to the medical profession is mainly regulated through public or administrative law. The bodies which are responsible for the registration might be of a quasi-public nature, but there is little direct involvement of private law.

The same applies to healthcare providers. Institutions that wish to provide healthcare services usually have to obtain some sort of license. Again, this is a public law requirement. The requirements that have to be fulfilled before licenses are awarded are laid down in legislation. Most Member States have supervisory agencies that monitor whether healthcare providers are complying with these requirements. In case of non-compliance, the agencies have powers under public law to (temporarily) close institutions or to order them to restrict their activities. The same applies to medical practitioners, who are also supervised and can be required to stop working in case of non-compliance. Whether the healthcare system is based on insurance or on universal provision of healthcare to all citizens, agreements will have to be made between the healthcare

[63] Interview with UEMS and CPME (Warsaw) on 19 February 2013.
[64] Directive 2005/36/EC of the European Parliament and of the Council on the recognition of professional qualifications.
[65] Articles 24-30 of the Professional Qualifications Directive.
[66] Interview with UEMS and CPME (Warsaw) on 19 February 2013.

buyers and healthcare providers. In that respect, private law plays a role since, depending on the nature of the healthcare system, these agreements can be of a contractual nature. This is perhaps the sole example of private law fulfilling a *ex ante* regulatory function. In the agreement, it can be agreed under what conditions healthcare services are delivered and with what standards they have to comply. However, the extent to which these agreements actually regulate standards and quality of care is unclear.[67]

When the doctor and patient meet, in the public healthcare system, they establish a relationship which is essentially of a private law character. In some Member States, this relationship creates both a contractual relationship and a relationship in tort, while in other Member States the private law character is solely expressed through the imposition of a duty of care in tort. However, in practice, this does not make a great difference, as the standard of care is usually similar in contract and in tort. Obviously, in private healthcare, the relationship between doctor and patient is contractual. The contract is then usually concluded with the clinic in which the treatment is provided. This also means that the substance of the contract, which has to be expressly concluded, becomes more important. Despite the private law character of the relationship between doctor and patient, public law still imposes certain duties on medical practitioners. These duties will often evolve around a duty to provide reasonable care – which is not too different from the duty imposed in contract or tort.

In general, it could be said that public law is mostly concerned with *ex ante* regulation of healthcare services. Private law, on the other hand, becomes relevant when something has gone wrong in the relationship between doctor and patient. The patient can then sue the doctor or healthcare provider in contract or in tort. Similarly, disciplinary law – which is difficult to place on the public law-private law spectrum – can also intervene *ex post*. While disciplinary proceedings are often started with a complaint from a patient, the character of the proceedings is less private in that the reputation of the medical profession as a whole is taken into account. Moreover, disciplinary proceedings are usually heavily regulated by public law. Certain Member States, such as Germany, have out-of-court dispute settlement procedures where liability disputes

[67] Interview with CZ (Tilburg) on 21 August 2012. For a discussion of the situation in the Netherlands, see R Halbersma, J van Manen en W Sauter, 'Voldoen verzekeraars in hun rol als motor van het zorgstelsel?', *NZA Research Paper* 2012-3, 20-21.

between medical practitioners and patients can be resolved without having to go through the court systems.[68]

What both public law and private law have in common in the healthcare sector is that they usually impose very broad and general obligations and duties on medical professionals and healthcare providers. These duties subsequently have to be defined more precisely. This specification of the duty of care of medical professionals – whether in public law or in private law – can be done *ex post* through judicial or disciplinary proceedings. A court will then be required to define the required standard of care. Alternatively, the required standard of care can be defined *ex ante* through some sort of standardisation. The healthcare sector is full of guidelines, standards and protocols. Some of these standards have been adopted at the international level, while others will be national. It is clear that, especially for scientific standards, there has been a process of internationalisation, which has frequently been encouraged by the United States.[69] This has also been recognised in the case law of the CJEU discussed above.[70] In many cases, the parties who are making medical standards draw from the same international scientific evidence. However, there is still a broad margin of appreciation in the interpretation of this evidence which can result in the adoption of different standards at the national level.[71] Such standards can apply to hospitals or to individual medical specialists. They will have a different status in medical practice, but in general they are not directly binding in law. They are used to define and specify the requirements imposed on healthcare service providers in public as well as private law.

C. European standardisation in national regulation of healthcare services

The link from national healthcare standardisation to European standardisation through CEN is then easily made. European standardisation could be one way of specifying the required duty of care of medical professionals in public or private law. However, this is where some caution is required. The way in which the Member States have organised medical standardisation differs significantly. Because of a lack of expertise of the public administration, it is understandable that medical professionals have to be closely involved in the standardisation process. However, the

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[68] C Katzenmeier, 'Außergerichtliche Streitbeilegung in Arzthaftungssachen' (2008) 58 *Anwaltsblatt* 819. See also P Weidinger, 'Aus der Praxis der Haftpflichtversicherung für Ärzte und Krankenhäuser – Statistik, neue Risiken und Qualitätsmanagement' (2006) 10 *Medizinrecht* 571.

[69] N Cortez, above n 34, 669.

[70] *Geraets-Smits* and *Peerbooms*, above n 25.

[71] N Cortez, above n 34, 656-657. See also R Blank and V Burau, 'Setting Health Priorities Across Nations: More Convergence than Divergence?' (2006) *27 Journal of Public Health Policy* 265 and T Marmor, R Freeman and K Okma, 'Comparative Perspectives and Policy Learning in the World of Health Care' (2005) 7 *Journal of Comparative Policy Analysis* 331.

extent to which they are autonomous in the standard-setting process depends on the Member State in question. In some Member States, such as the United Kingdom, medical standardisation is strictly controlled by the State.[72] Although it will always be doctors who define the standards, they are brought to work in a standardisation framework which is strictly publicly supervised. This means that such standardisation is not really private regulation, but more co-regulation under public supervision. The intention behind this is that self-regulation cannot exclusively be relied on to produce outcomes which are beneficial to the public good.[73] There has to be public accountability and control.[74] Therefore, the State is in control of the organisation of the process and of the incorporation and application of the standards in the healthcare sector. Public supervisory agencies act on the basis of these standards, or even on the basis of standards which they have made themselves.[75] This public responsibility for medical standardisation cannot be seen in all Member States. For example, in the Netherlands, much more reliance is placed on the medical profession itself, without too much supervision or hierarchy. It is strongly believed that the medical profession itself should be responsible for the making of standards in the healthcare sector.[76] Public supervisory agencies will rely on these standards in their supervisory activities, but they exercise no influence on the making of them. As a consequence, the Dutch system clearly recognises the autonomy of the medical profession in deciding when, how and which standards have to be set. However, it has also become clear that the profession itself cannot be entirely relied on to make sufficient and adequate medical standards. Therefore, the Netherlands has now introduced a Quality Institute for Healthcare.[77] This institute will not get involved in the actual standard-making process, but it will set out how medical standards should be made and it will provide a public stamp of approval to standards that have complied with their requirements. Moreover, the institute has been granted the power to force the medical profession to start working on a standard if it considers it necessary that a standard be developed.[78] As such, the institute could issue a "top-down" mandate to the profession, which would be a similar to Commission mandates in the New Approach. However, the institute would not get involved in

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[72] For a comparative perspective, see D Ngo et al. (eds), *Supervising the Quality of Care in Changing Healthcare Systems: An International Comparison*, Department of Healthcare Governance, Erasmus University Rotterdam, August 2008. For the UK perspective, see E Scrivens, *Quality, Risk and Control in Health Care* (Maidenhead, Open University Press, 2004) and G Bevan, 'Changing paradigms of governance and regulation of quality of healthcare in England' (2008) 10 *Health, Risk and Society* 85.

[73] E Scrivens, above n 72, 139-140.

[74] K Syrett, 'Nice Work? Rationing, Review and the 'Legitimacy' Problem in the New NHS' (2002) 10 *Medical Law Review* 1. See also E Scrivens, above n 72, 120-127.

[75] For an example in the UK, see the Care Quality Commission: www.cqc.org.uk.

[76] Interview with Quality Institute for Healthcare (Diemen) on 23 August 2012. For the Dutch perspective, see Regieraad Kwaliteit van Zorg, *Een Visie op Richtlijnontwikkeling in Nederland*, The Hague, April 2010. See also J van Everdingen et al. (eds), *Evidence-based richtlijnontwikkeling: een leidraad voor de praktijk*, (Houten, Bohn Stafleu, 2004).

[77] Quality Institute for Healthcare: www.zorginstituutnederland.nl/kwaliteit/het+kwaliteitsinstituut.

[78] Interview with Quality Institute for Healthcare (Diemen) on 23 August 2012.

the actual substance for the standard – this would remain within the control of the medical profession.[79] If the Dutch system is compared with the UK system, it is clear that there is a difference in professional autonomy in the two countries. In the UK, the standardisation process is tightly controlled and supervised by public authorities, which are also involved in the standardisation process. As a result, the medical standards that are developed will take more interests into account than just the purely medical scientific issues. This is not necessarily the case in the Netherlands, where medical standardisation remains primarily a scientific evidence-based exercise. The subsequent policy questions which have an inevitable impact on medical practice are not directly dealt with in the standardisation process.

Overall, the lesson which should be learnt from the national systems is that there are significant differences in the extent to which Member States allow private regulation to play a role in the regulation of healthcare services. This is not the same as the scope of private law – private law will always have a role to play through contract and tort law. However, certain Member States have created very public structures of medical standardisation. This might mean that European standardisation of healthcare services, which essentially remains private regulation, might not easily be accepted in these Member States. As a result, one has to look at the scope of private regulation at the national level. If the scope of private regulation is limited, this could result in Member States objecting to European standardisation. This would be likely to have an impact on whether or not they approve European standardisation projects. Consequently, it would be more likely to have an impact on the making of European standards than on their application. However, this would also depend on the question to what extent public authorities get involved in (blocking) European standardisation initiatives in the healthcare sector. This is something that will be discussed in the next section.

III. THREE CASE STUDIES ON EUROPEAN STANDARDISATION OF HEALTHCARE SERVICES

A. Aesthetic Surgery Services

In April 2010, a European standardisation process for Aesthetic Surgery Services was started through CEN. The initiative had been submitted by a number of Austrian plastic surgeons to the Austrian Standards Institute ("ASI"), which was also to act as secretariat to the standardisation

[79] Ibid.

process.[80] Two key reasons for the standardisation project can be identified. First of all, aesthetic surgery has become a highly profitable market. This is also clear from the PIP breast implants case, which will be discussed below. Aesthetic surgery is usually provided by private healthcare providers outside the public healthcare system. There is a significant amount of advertisement; treatments are voluntary and easy to obtain. This means that the patient is not really a patient but more of a consumer.[81] This consumer is prepared to travel across borders for treatment. As a result, it is possible to say that aesthetic surgery takes place in a market, which is somewhat removed from the traditional public healthcare systems. Furthermore, the market is truly European, or even international. Secondly, the medical professionals which operate on this market have very different qualifications. Various medical specialties perform treatments which could be described as aesthetic surgery. Plastic surgeons are the main specialty that has entered the aesthetic surgery market, but dermatologists, ENT-surgeons and even general practitioners also operate on the market.[82] Moreover, it is possible for doctors with basic training to be involved in aesthetic surgery. In some Member States it is even possible for nurses to perform aesthetic surgery.[83] As a consequence, the market is full of different service providers. Some do not have a fixed location and travel from one Member State to another with their products and materials.[84] Some of them have decided to call themselves cosmetic surgeons, which in many Member States is not a protected title.[85] This could create confusion for patients, as the use of the term surgeon would imply specialist training as a surgeon. This is just one example of a lack of regulation of aesthetic surgery services at the national level. The only Member State which has a very clear regulatory framework is France, in which it is provided by law that all aesthetic surgery treatments have to be performed under the supervision of a plastic surgeon.[86] In Denmark, medical professionals who want to get involved in aesthetic surgery first have to receive certification.[87] Following the PIP breast implants scandal, the cosmetic surgery sector has come under the attention of national regulatory agencies which, in cooperation with the EU, are working to fill regulatory gaps and to tighten the regulation of the aesthetic surgery sector.[88] The European standardisation process also seeks to play a role in this regulatory framework.

[80] Interview with Chairman of Dutch Mirror Committee for Aesthetic Surgery Services (Goes) on 29 December 2012.
[81] Ibid.
[82] Ibid.
[83] Ibid. and Interview with ASI (Vienna) on 12 November 2012.
[84] Ibid.
[85] Ibid.
[86] Ibid.
[87] Ibid.
[88] Ibid.

However, one could wonder to what extent the European standardisation initiative has already been overtaken by legislative initiatives at the national level, such as in the UK.[89]

Although the standardisation process covers the complete doctor-patient relationship – including, for example, issues as consent – its main focus is twofold. First, the European standard intends to regulate which medical professionals can perform which treatments. It introduces a number of competences medical professionals must have obtained before they can perform certain treatments.[90] The standard has a list with treatments, which have all been given a certain risk factor. Treatments with a higher risk factor can only be performed by medical professionals with more advanced training and experience. Second, the standard sets out what facilities a medical professional must have before certain treatments can be performed.[91] A distinction is made between treatments that can be performed in a treatment room and treatments that require an operating theatre. As such, the standard would prevent doctors from treating consumers at their home. Treatment would have to be provided at a location with a certain minimum of facilities. Overall, the focus of the European standard is on the "by whom" and "where" of aesthetic surgery services. The standard does not directly deal with the "how" of aesthetic surgery.[92] As a result, those who are involved in the standardisation process seek to distinguish this standard from evidence-based medical standards, which would set out how specific treatments have to be performed on the basis of scientific evidence.[93] According to them, a distinction should be made between standardising the medical procedure and the medical process.[94] This standard only deals with the process. This does not mean that the standard should not be based on sound medical evidence – however, it is different in nature from evidence-based medical standards. Those who oppose European standardisation argue that the very inclusion of certain aesthetic surgery treatments in the standard already requires scientific evidence and that the standard might appear to justify certain treatments for which there is no legitimate basis in scientific evidence.[95]

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[89] In the UK, a report was published by a Commission chaired by Sir Bruce Keogh: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192028/Review_of_the_Regulation_of_Cosmetic_Interventions.pdf.
[90] Articles 3 and 7 of Draft prEN 16372:2012 'Aesthetic Surgery and aesthetic non-surgical medical services'.
[91] Articles 5 and 7 of Draft prEN 16372:2012 'Aesthetic Surgery and aesthetic non-surgical medical services'.
[92] Interview with Chairman of Dutch Mirror Committee for Aesthetic Surgery Services (Goes) on 29 December 2012 and Interview with ASI (Vienna) on 12 November 2012.
[93] Ibid.
[94] Ibid.
[95] Interview with UEMS and CPME (Warsaw) on 19 February 2013.

Twenty-two Member States are involved in the standardisation process.[96] They all have created national mirror committees to be able to represent the national positions at the European level. In addition, a number of international and European organisations are participating with liaison status. This means they participate in the meetings, but they have no active voting rights. Certain sections of UEMS – committees representing a particular medical specialty – also participated in the meetings. However, they did so without the explicit support of UEMS and, after the draft standard had been published in May 2012, it became clear that UEMS would withdraw any (implicit) support of the standardisation process.[97] It also asked CEN to refrain from referring to UEMS syllabi or other documents in the European standard.[98] This was the first public opposition to the standard. However, there had already been significant tensions in the standardisation process. They were mainly caused by the different positions of the stakeholders in the various Member States – both of the medical profession and the various public bodies involved in the supervision of the healthcare sector. These positions were highly dependent on the national regulatory frameworks. Because France already has legislation in place that provides that only plastic surgeons can provide aesthetic surgery services, the French position in the standardisation process has been to protect the French legislation.[99] This has primarily been done by ensuring a significant amount of a-deviations, which clarify which aspects of the European standard might not comply with the French legislation.[100] This is a fundamentally different position from ensuring that aesthetic surgery services are adequately regulated by creating a good quality standard. A similar position has been taken by Denmark and Germany.[101] The UK, the Netherlands and Austria have been the main supporters of the standard and have provided most of its input.[102]

A draft standard was published in early 2012.[103] After the various comments had been received, it became clear in September 2012 that the standard would not have sufficient support – the required 71% of the votes – to be adopted.[104] A period of reflection was started. It was decided to make a clearer distinction between aesthetic surgery services and non-surgical aesthetic

[96] Interview with ASI (Vienna) on 12 November 2012.
[97] Interview with ASI (Vienna) on 12 November 2012..
[98] Letter sent by UEMS to CEN on 22 May 2012.
[99] Interview with ASI (Vienna) on 12 November 2012.
[100] Interview with Chairman of Dutch Mirror Committee for Aesthetic Surgery Services (Goes) on 29 December 2012.
[101] Ibid.
[102] Ibid.
[103] Draft prEN 16372:2011 Aesthetic Surgery Services.
[104] Interview with Chairman of Dutch Mirror Committee for Aesthetic Surgery Services (Goes) on 29 December 2012.

services. A new draft standard was published in December 2012,[105] which required a new CEN enquiry which took place until May 2013. The new comments were resolved in September 2013. However, it was not until October 2014 when the final vote took place. The standard was formally adopted in December 2014 and is now available through the national standardisation organisations.

From the start European medical associations have been vehemently opposed to the standardisation process. Their opposition is based on, on the one hand, criticism of the suitability of European standardisation through CEN as a regulatory tool in the healthcare sector and, on the other hand, on specific concerns about the standardisation process for aesthetic surgery services.[106] In early 2011, the President of the Comité Permanent de Médicins Européens ("CPME") visited CEN to express the strong view of his organisation that CEN should not enter the healthcare sector.[107] He considered it undesirable for CEN to enter a field which should remain in control of the medical profession. In September 2012, a common position was adopted by a number of European medical associations which rejected the possibility of standardisation through CEN in the healthcare sector.[108] The concerns were threefold.[109] Firstly, the standardisation process of CEN was fundamentally incompatible with traditional methods of medical standardisation based on scientific evidence. It would open up the possibility of non-medical concerns having an impact on the standardisation process, which would not result in optimum medical care. Such standardisation would endanger the autonomy of the medical profession. Secondly, it would not be compatible with the principle of subsidiarity. Thirdly, it would be in breach of the explicit rejection of EU competence to regulate healthcare services in Article 168 TFEU. The latter two objections do not appear to be legally correct, as they are based on a misunderstanding of CEN's role at the European level and the legal status of standardisation. However, the medical associations argued that there is a strong top-down element to the standardisation process and that it would be likely that the European standard would be made legally binding in one way or another.

These general concerns were supplemented by specific concerns about the standardisation process for Aesthetic Surgery Services. The first concern was that the standardisation process

[105] Draft prEN 16372:2012 Aesthetic Surgery and aesthetic non-surgical medical services
[106] Interview with UEMS and CPME (Warsaw) on 19 February 2013.
[107] Interview with CEN (Brussels) on 4 April 2012 and Interview with UEMS and CPME (Warsaw) on 19 February 2013.
[108] Joint Resolution Standards in Medical Practice (14 September 2012).
[109] Ibid.

had insufficient procedural safeguards to ensure that the standards that would be set would be based on sound scientific evidence.[110] The European standardisation process could be abused to provide a sense of medical legitimacy to aesthetic surgery treatments that were not in fact evidence-based.[111] Furthermore, the standardisation process and its revision process were too slow to ensure that the standard would always be based on up-to-date medical evidence. The second concern was that the standardisation process would be used to establish aesthetic surgery as a separate medical specialty.[112] This had previously been tried through UEMS, but UEMS had resisted and refused to recognise aesthetic surgery as a separate specialty.[113] The result of this could be that European standardisation would now be used to achieve the same result and essentially to engage in some sort of market protection and restriction of the market by reserving treatments to this new quasi-specialty. It would provide a route to a small group of medical doctors to restrict the aesthetic surgery market to a limited group of doctors.[114]

B. Cleft Lip Surgery Services

In December 2010, BDS, the Bulgarian standardisation organisation, submitted a proposal to CEN for a European standard on Cleft Lip Surgery.[115] The initiative was submitted to BDS by the European Cleft Organisation ("ECO"), a European patient organisation which seeks to promote high-quality medical care for babies born with cleft lips throughout Europe. It had specifically chosen BDS as the standardisation organisation to administer the process, since this would help to raise awareness for the standardisation process in the new Member States.[116]

ECO is a European organisation for cleft patients throughout Europe. The organisation is run by a group of cleft patients and medical doctors. Its main aim is to ensure that there are minimum standards for cleft lip treatment in all EU Member States. It recognises that standards of care are widely divergent in the EU, but it argues that all EU citizens should be entitled to a minimum level of care.[117] Its position is that this minimum level of care is not provided in all EU Member States.[118] It is dissatisfied with the quality of care provided in certain Member States, in particular Bulgaria and Romania. To remedy this, ECO is involved in the training of medical

[110] Interview with UEMS and CPME (Warsaw) on 19 February 2013.
[111] Ibid.
[112] Ibid.
[113] Ibid.
[114] Ibid.
[115] BT N 8561- (Draft Resolution BT C4/2011), Issue date : 2011-01-13.
[116] Interview with ECO (Skype) on 14 March 2012.
[117] Ibid.
[118] Ibid.

specialists and nursing personnel in a number of new Member States.[119] It has developed and coordinated training programmes. There are very few standards on cleft lip treatment in these Member States and the level of research is much less advanced than in some of the older Member States. For these reasons, ECO believed that it would be good to have a European standard that would set out the minimum level of care required for patients with cleft lips.[120] Cross-border movement of patients is not a realistic possibility for babies born with clefts. Because of a lack of financial resources, patients in the new Members are not able to travel to the old Member States for treatment.[121] In addition, babies born with clefts need a series of treatments, which would make cross-border movement for treatment difficult – if not impossible. For that reason, the Cross-Border Healthcare Directive 2011 is not of much practical help. A European standard could help to raise the overall level of care throughout the EU. Furthermore, it would empower patients to require a certain level of care from the doctors in their home Member State.

The aims of the standardisation initiative were clearly put in the proposal submitted to CEN in December 2010:

"The benefits of standardisation in this field will be the establishment of a clear and accurate specification of the healthcare management process for infants born with clefts. A European Standard will help to reduce the health inequalities in the EU countries and support patients' safety"[122]

For some time, ECO had thought about which route could best be taken to develop such a standard. As a patient organisation, it was in a more difficult position than associations of medical doctors, which have traditionally been involved in the making of their own evidence-based standards for medical treatment. The route a patient organisation had to take if it wanted to initiate a standard on cleft lip treatment was not immediately clear. One of the members of ECO's board was a surgeon in the United Kingdom who had previously been involved in the creation of standards for medical devices through CEN.[123] As a result, the attention of ECO was drawn to CEN. In the end, ECO decided that a standardisation process through CEN would be a suitable means to achieve its aim of realising a minimum level of care in all EU Member States.[124]

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[119] Ibid.
[120] Ibid.
[121] Ibid.
[122] BT N 8561- (Draft Resolution BT C4/2011), Issue date : 2011-01-13.
[123] Interview with ECO (Skype) on 14 March 2012.
[124] Ibid.

ECO was very much aware that this was an experimental process, but for three reasons it considered a standardisation process through CEN to be particularly worthwhile. Firstly, the standardisation process would bring together at the European level various stakeholders involved in cleft care. The standard would derive a sense of authority from this consensus-based process.[125] At the time of the initiative there were too many standards throughout Europe, none of which had particular authority over other standards. CEN would provide a mechanism to develop a standard that would potentially be authoritative in all Member States. Secondly, the standard would help to create a degree of consistency. Although ECO would never claim that there should be one uniform treatment process provided to all cleft patients in the EU, there should at least be consensus about the minimum level of care which has to be provided to all patients.[126] Thirdly, and finally, ECO recognised that a CEN standard would not override national legislation. As such, the fact that national legislation would be very different in the various Member States would not cause any direct difficulties.[127]

The care of babies born with cleft lips is not a market. Unlike aesthetic surgery, cleft lip care is still very much provided by public hospitals as part of public healthcare systems. Therefore, it could be expected that cleft care can more easily be exclusively regulated by the medical profession through traditional methods of medical standardisation based on scientific medical evidence. However, it is apparent from this initiative that, from the perspective of a European patient organisation, there are significant differences in knowledge and expertise within the Member States. The proposal for a European standard involved the linking of national structures of medical standardisation through opening up national medical standardisation to a European market. CEN would be used as a catalyst for this process.

After the submission of the proposal to CEN, the national standardisation organisations had to consult with their stakeholders. These meetings took place in early 2011 and in April 2011 all national standardisation organisations voted on the proposal.[128] Five Member States voted against the proposal, while fifteen Member States voted in favour. Eleven Member States abstained. Because of CEN's weighted voting procedures the proposal was rejected. The Member States that voted against the proposal were Finland, France, Germany, the Netherlands and Spain.[129] Broadly speaking, three categories of objections can be identified: (i) healthcare

[125] Ibid.
[126] Ibid.
[127] Ibid.
[128] Voting Results: *"Creation of a new CEN Project Committee on 'Healthcare services for cleft lip and/or palate'"*, CENBT/8561, Brussels, April 2011.
[129] Ibid.

services provided in public healthcare systems should be regulated by the State without interference of private regulation; (ii) European standards would lower the level of care provided in some of the old Member States; (iii) European standardisation would not be the right mechanism to create standards for healthcare services.

After the negative vote, ECO organised a number of meetings in France and Spain to increase the support for a European standardisation process in late 2011 and early 2012.[130] In May 2012 it became clear that, after some additional meetings with national stakeholders, there would still not be sufficient support to start a European standardisation process.[131] ECO then considered the possibility of creating a Workshop Agreement through CEN. This would not have the same status as a European standard, but could potentially be a first step towards a European standard. However, even the possibility of a Workshop Agreement was (informally) rejected by a number of standardisation organisations.[132] As an alternative, ECO decided to develop a Technical Report through CEN, using ASI as the secretariat.[133] The first meeting was held in Vienna in September 2013. A Technical Report does not have the same status as a European standard – it is even softer than a European standard –, but it can still be used to lay down standards for services. In May 2015, the Technical Report was finally adopted.[134]

C. PIP breast implants[135]

The third case study in this chapter is the PIP breast implants scandal. It is not directly concerned with European standardisation of healthcare services. Breast implants are considered medical devices and come within the scope of the New Approach. However, because they are closely linked to aesthetic surgery services and form an important part of the next chapters, an introduction to the role of European standardisation in the PIP breast implants scandal will be provided in this chapter.

In the last decades, breast implants have become a very popular product for women throughout the world. The PIP factory, located in France, was one of the main producers of breast implants in Europe, and possibly even in the world. It started producing breast implants in the early 1990s. At some point in the early 2000s, PIP started having financial difficulties and decided to

[130] Interview with ECO (Skype) on 14 March 2012.
[131] Interview with ECO (Skype) on 2 May 2012.
[132] E-mail correspondence with ECO on 14 March 2013.
[133] E-mail correspondence with ECO on 8 April 2013.
[134] Technical Report on care services for babies born with cleft lip and/or palate (CEN/TR 16824:2015).
[135] This case study is based on an article that has been published in the European Journal of Risk Regulation: B van Leeuwen, 'PIP Breast Implants, the EU's New Approach for Goods and Market Surveillance by Notified Bodies' (2014) 3 *European Journal of Risk Regulation* 338.

develop an ingenious strategy to cut costs. Instead of filling the breast implants with the required medical silicone gel, PIP started to use industrial sub-standard industrial silicone gel in the production process. This was obviously significantly cheaper. Unfortunately, it is still unclear how systematic the use of sub-standard industrial silicone gel was – it seems that certain badges of PIP implants contained only the required medical gel, while others contained a mix or only industrial gel. The randomness of the production process has made it much more difficult to identify risks and has led to significant delay in taking action against PIP.

In any event, sub-standard PIP breast implants were distributed throughout the EU for a significant period of time. In 2009, the first concerns that the breast implants might be defective were raised in France.[136] However, it was not until 2011 that the French public supervisory agency responsible for medical devices, AFSSAPS,[137] issued a warning and that PIP breast implants were taken off the market. By that time, many thousands of women had already received PIP breast implants. They were faced with great uncertainty – there was no way for them to find out whether the breast implants that they had received were sub-standard. Sometimes it was not even possible for them to be sure whether or not their implants had been produced by PIP.[138] Furthermore, a medical report that had been written at the request of the European Commission stated that although the PIP breast implants might have a higher risk of rupture, it could not be proved that there were any particular health risks associated with the higher risk of rupture (such as a higher risk of cancer).[139] Faced with this uncertainty, many women decided to have their breast implants removed. In some situations, the removal of the breast implants was covered by their health insurance. However, most of the time, health insurers – whether public or private – refused to pay the removal costs if the original decision to have breast implants was based purely on aesthetic reasons and not on a medical indication.[140] Some cosmetic surgery clinics offered to remove the breast implants at cost price or even for free. However, they would still require women to pay for the costs of new breast implants. As a consequence, many women had to pay a significant amount of money as a result of having received – or possibly having received – defective breast implants. Moreover, there was a

[136] Judgment of Tribunal de Commerce in Toulon of 14 November 2013 (N° de rôle: 2011F00517).
[137] Agence française de sécurité sanitaire des produits de santé, which is now called the Agence Nationale de Sécurité du Médicament et des Produits de Santé.
[138] Interview with VKI (Vienna) on 5 November 2013.
[139] European Commission, Scientific Committee on Emerging and Newly Identified Health Risks, 'Preliminary Opinion on the safety of Poly Implant Prothèse (PIP) Silicone Breast Implants (2013 update)', September 2013, http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_038.pdf.
[140] Interview with VKI (Vienna) on 5 November 2013.

possibility of psychological harm. For all of these reasons, it is understandable that women wanted to seek legal redress.

To be able to understand the various litigation strategies that have been pursued after the PIP breast implants scandal, it is important to understand the regulatory framework in which the breast implants were marketed and distributed. The regulatory framework of the New Approach has been introduced in chapter 3. Breast implants are considered medical devices and, as such, come within the New Approach.[141] The Medical Devices Directive[142] lays down the essential requirements which breast implants have to fulfil,[143] while the specific technical requirements have been laid down in a European standard adopted through CEN.[144] Before medical devices can be placed on the market, the manufacturer must attach the CE marking to goods and issue a declaration of conformity, declaring that the goods comply with the provisions of the Directive – and, necessarily, of the European standard.[145] A notified body then has to inspect the manufacturer's quality system and design dossier.[146] Each Member State has to notify to the European Commission which bodies can fulfil this role in their country – hence the term "notified body". Once a notified body has approved the quality system and design dossier the product can be placed on the market. The notified body will then continue to undertake regular surveillance of the quality system.[147] In the case of PIP, the notified body was TÜV Rheinland, a large German certification body. It is not necessary for a manufacturer to obtain the approval of a notified body in their own Member State – it is possible to choose a notified body in another Member State. The conformity assessment by the notified body focusses solely on the quality system and the design of the product. Therefore, there is no direct control of whether the medical devices actually comply with the specific provisions of the European standard. The assessment focusses exclusively on the quality system and the design dossier in place. In addition to the role of notified bodies, an important function is performed by national supervisory agencies, which are responsible for surveillance of the market.[148]

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141 Commission Directive 2003/12/EC on the reclassification of breast implants in the framework of Directive 93/42/EEC on medical devices.

142 Council Directive 93/42/EEC concerning medical devices ("the Medical Devices Directive").

143 Articles 3 and 5 and Annex I of the Medical Devices Directive.

144 In this case, EN ISO 14630:2009 Non-active surgical implants - General requirements and EN ISO 14607:2009 Non-active surgical implants - Mammary implants - Particular requirements.

145 Article 17 of the Medical Devices Directive.

146 Article 11 and Annex XI of the Medical Devices Directive.

147 Article 5.1 of Annex II of the Medical Devices Directive.

148 Article 10 of the Medical Devices Directive.

In a case like the PIP case, there are a number of parties a case could be brought against to claim damages. The most probable defendant would be the PIP factory or its management. However, rather unsurprisingly, the PIP factory had gone into liquidation in 2010. Furthermore, the owners of the factory did not have any traceable assets and criminal proceedings were brought against the management of the factory before the Tribunal de Grand Instance in Marseille. In December 2013, the main owner of the factory, Jean Claude Mas, was sentenced to four years' imprisonment.[149] Therefore, bringing a case against the management also had little chance of success. Many victims joined the criminal proceedings as victims, which meant that they were able to claim compensation from a criminal compensation scheme developed by the French State.[150] Although compensation by this scheme is limited to 3000 euros, it meant that the victims would obtain at least some redress.

In light of the difficulties in suing PIP or its management, different litigation strategies have been pursued in various Member States. The Austrian consumer organisation VKI has brought proceedings against Allianz, a German insurer with which PIP had obtained insurance.[151] As the insurance contract was concluded with the French subsidiary of Allianz, the proceedings have been brought in Paris by a French lawyer who is instructed by VKI. The claim has been brought on behalf of around 70 Austrian victims. A number of legal issues have to be decided first by the French court.[152] First of all, it is uncertain whether a valid insurance contract has been concluded between Allianz and PIP. Allianz submits they it has been deceived by PIP as to the nature of the product and the production process.[153] As a consequence, the insurance contract would be void. Secondly, Allianz claims that there is a clause in the contract which excludes residents outside France from the scope of the insurance contract. This would mean that the damage incurred by the Austrian victims would not be covered by the insurance contract.[154] The Paris court still has to decide these preliminary issues. In a separate judgment in 2012, the Tribunal de Commerce in Toulon held that the deceit by PIP did not invalidate the insurance contract between Allianz and PIP and that there was a valid insurance contract in place. However, it is clear that the case against Allianz remains complicated. An alternative strategy has been to sue TÜV Rheinland, the German certification company. A group of victims have brought proceedings against TÜV for its alleged failure to carry out the required surveillance and

[149] Judgment of the Tribunal correctionel in Marseille of 10 December 2013, (N° minute: 7206/13), (N° parquet: 12048000148).
[150] Interview with VKI (Vienna) on 5 November 2013.
[151] Ibid.
[152] Ibid.
[153] Ibid.
[154] Ibid.

inspections at the PIP factory. The case has been brought in tort – it is claimed that TÜV has breached the duty of care which it owed to the women who received PIP breast implants. In the UK, claimants have started group litigation against a number of clinics and individual surgeons who had provided PIP breast implants to them. The litigation is based on the contract between the patients and the clinics in which they received the breast implants. It is claimed that the breast implants were not of satisfactory quality. Overall, different strategies have been pursued in various Member States. These strategies will be analysed in chapter 6.

IV. THE INTERACTION BETWEEN EUROPEAN STANDARDISATION AND HEALTHCARE SERVICES

A. Traditional evidence-based medical standardisation and European standardisation through CEN

Medicine and standardisation is not a natural combination. Medical doctors are one of the traditional professions.[155] As a result, there is a very strong emphasis on the autonomy and integrity of the profession. Medical knowledge is made, maintained and developed within the medical profession, which has created its own structures to communicate and protect this knowledge.[156] External interference with these structures of knowledge is deemed to be an attack on the integrity of the profession. In addition, doctors place strong reliance on the individual nature of the relationship between doctor and patient. They have sworn the Hippocratic Oath, which means they must always act in the best interests of the individual patient. This is one of the founding pillars of medical practice. The primary "standard" among medical doctors is that the interests of the individual patient should always prevail over existing standards or guidelines.

These two principles – professional autonomy and individualism – could appear to be fundamentally inconsistent with any kind of attempt to standardise medical practice. At the same time, doctors also recognise that it is in the interests of patients to share medical knowledge and to create medical standards with guidelines on best practice.[157] However, these standardisation activities are a special kind of standardisation and are based on two fundamental pillars.[158] Firstly, the development of medical standards should be in the exclusive control of the medical profession itself. The creation of medical standards is an evidence-based medical science for

[155] E Freidson, *Profession of Medicine: A Study of the Sociology of Applied Knowledge* (Chicago, UCP, 1988).
[156] Interview with UEMS and CPME (Warsaw) on 19 February 2013. See also E. Freidson, above n 155, 137-157.
[157] Ibid.
[158] Ibid. See also E Freidson, above n 155, 137-157.

which only the medical profession has the necessary knowledge and experience. The inclusion of other, non-medical interests in the setting of medical standards would not be in the best interests of patients and would not result in the provision of optimum medical care.[159] Secondly, the standards developed by the medical profession should not obtain strict binding force. This is because they are always inferior to the primary standard among doctors – that the individual patient should be treated as an individual case and in their best interests. A doctor must always be able to reject a standard and to depart from a standard in the best interests of the individual patient.[160] The medical profession has developed a principle for this: the "comply or explain" principle. In principle, doctors expected to comply with existing medical standards. There is a presumption of compliance. At the same time, it must always be possible for doctors to refuse to follow a particular standard in an individual case. However, there is a professional burden on the doctor to explain why the standard was not followed in the circumstances of the case.[161]

In the Cleft Lip Surgery example, the key problem is that there are many medical standards that deal with aspects of the treatment of babies born with cleft lips. There are both international, European and national standards for cleft lip treatment. This is the direct result of the fact that there is very little consensus about how babies with cleft lips should be treated. In Member States with less medical expertise, such as in Eastern Europe, this could lead to uncertainty about which guidelines should be applied and a preference for minimum standards that would reduce costs. Therefore, the European standardisation process through CEN is used as a facilitator to bring some order in the existing medical standards and to assist the new Member States with adopting a coherent and good quality guideline. CEN could help to provide substance to the concept of international scientific evidence developed by the CJEU.[162] However, at the same time, the process has shown that if there is insufficient agreement about the status of international science, it is unlikely that European standardisation will be successful. Although Bulgaria and Romania would benefit from more international input in medical standardisation, there are insufficient incentives for medical professionals in other Member States to export their international science to the new Member States. Furthermore, they do not believe that European standardisation through CEN would be the right way to do this, since the standardisation process through CEN does not have sufficient safeguards to guarantee that the standards which are produced are evidence-based.

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[159] Ibid. and Interview with NEN (Delft) on 12 April 2012.
[160] Interview with UEMS and CPME (Warsaw) on 19 February 2013. See J van Everdingen et al. (eds), *Evidence-based richtlijnontwikkeling: een leidraad voor de praktijk* (Houten, Bohn Stafleu, 2004), 75-76.
[161] See A Samanta, J Samanta and M Gunn, 'Legal Considerations of Clinical Guidelines' (2003) 96 *Journal of the Royal Society of Medicine* 133, 137.
[162] See A den Exter, above n 33.

The situation is different for Aesthetic Surgery Services. The problem there is that aesthetic surgery has emerged as a new field of medicine. Practitioners in this new sector do not feel bound by existing medical standards, because they do not cover their new specialty. The medical professional associations deny that there is a lacuna because they do not consider aesthetic surgery as a separate specialty – the sector is already sufficiently covered by medical standards for plastic surgery, ENT surgery and dermatology. From that perspective, European standardisation through CEN would be unnecessary and a threat to existing medical standards. At the same time, those in favour of the standardisation process argue that market forces have resulted in dangerous practices in the aesthetic surgery sector and that, with the traditional medical standardisation routes being blocked by the professional associations, European standardisation through CEN has become the only realistic alternative to impose some regulation on a sector which has *de facto* become self-standing.

With respect to methodology, most Member States or associations of medical professionals have developed methods to ensure that any medical standards are based on sound medical evidence.[163] This methodology has been adopted from institutes in the United States, which were frontrunners in the field of evidence-based medicine. [164] The medical standardisation process starts with a thorough search of the available medical literature on the topic of the standardisation. After this search, the participants in the standardisation process have to make a qualitative analysis of the literature. They have to decide, on the basis of their professional judgment, which studies are relevant and which studies are not relevant, and they have to decide which studies provide sufficient medical and scientific basis to serve as inspiration for the standardisation process.[165] It is expected that throughout the standard references are made to the relevant literature. Furthermore, the standard has to explain how the literature supports the guidance, or why a particular study or strand of the literature has not been followed in the standard.[166] All of this means that scientific evidence plays a key role in medical standardisation. The parties that are involved in medical standardisation still need to reach consensus on the basis of the literature. They are also expected to use their professional judgment to decide on the weight of the literature. However, in the end, the consensus has to be based on scientific evidence. No such requirements exist for European standardisation through CEN. Although medical literature will play a role in the process, the process is inherently less scientific. The

[163] P Shekelle et al., 'Clinical Guidelines: Developing Guidelines' (1999) 318 *British Medical Journal* 593.
[164] J van Everdingen et al. (eds), above n 160, 14-15.
[165] P Shekelle, above n 163. See also J van Everdingen et al. (eds), above n 160, 145-157.
[166] J van Everdingen et al. (eds), above n 160, 158-171.

safeguards that exist in traditional medical standardisation do not exist in European standardisation.

This is readily acknowledged by participants in European standardisation processes in the healthcare sector – the evidence-based nature of the European standard for Aesthetic Surgery Services is rather slim.[167] Their response to any criticism is that European standardisation through CEN is a different kind of medical standardisation that does not focus on the medical procedure, but more on the entire process of the doctor-patient relationship.[168] The standards would not be about how the doctor should treat the patient, but more about the entire relationship between patient and doctor. This relationship involves many issues which are not scientific and which do not have to be evidence-based. The question what information should be provided to patients and what facilities should be offered to patients does not (always) have to be evidence-based. Such European standards would then be supplementary, or additional, to evidence-based medical standards. However, the medical profession claims that it is never entirely possible to distinguish between procedure and process. Furthermore, such process-based standards have a direct impact on the medical procedure. There is a real risk that European standardisation could be used to circumvent traditional medical standardisation and to impose standards which could not realistically be made through traditional medical standardisation.[169] This is confirmed by some other recent European standardisation initiatives in the healthcare sector. The chiropractors were the first profession to make a healthcare services standard through CEN and the osteopaths quickly followed in their footsteps.[170] For these professions, European standardisation constitutes an attractive mechanism to provide a sense of professional legitimacy to healthcare services that are not evidence-based.[171] While this should not be a direct problem for the medical profession, it becomes more of a problem when the medical profession itself directly engages in European standardisation, such as in the Aesthetic Surgery Services project.

Another element of traditional medical standardisation that cannot easily be accommodated in the European standardisation process is authorisation. For evidence-based medical standards, authorisation, or verification, by the appropriate medical associations is a key requirement to the

[167] Interview with Chairman of Dutch Mirror Committee for Aesthetic Surgery Services (Goes) on 29 December 2012 and Interview with ASI (Vienna) on 12 November 2012.
[168] Ibid.
[169] Interview with UEMS and CPME (Warsaw) on 19 February 2013.
[170] EN 16224: 2012 Healthcare Provision by Chiropractors, and EN 16686: 2016 Osteopathic service provision.
[171] See H Willensky, 'The Professionalization of Everyone' (1964) 70 *American Journal of Sociology* 137.

standard obtaining a status as the relevant professional standard.[172] This is both from the professional as well as from the legal point of view.[173] The standard must have been accepted by the profession as the appropriate standard before it comes into force in the sector. There is no such requirement for European standardisation. In fact, in the examples discussed above, the interaction between the European standardisation and the relevant medical associations was extremely tense. It is highly unlikely that authorisation would take place after the strong objections from within the medical profession. Therefore, it is less likely that the European standard will be applied in the regulation of healthcare services at the national level.

B. European standardisation and de-professionalisation of the medical profession

Closely linked to the discussion of the non-evidence-based nature of European standardisation is the argument that European standardisation would lead to de-professionalisation of the medical profession. This has become evident in the standardisation process for Aesthetic Surgery Services. There is a real fear among the medical profession that European standardisation would be used as a tool for anti-competitive protectionism. This is particularly caused by the fact that aesthetic surgery services are provided in a market. Such protectionism would reduce medicine to all other services that are exposed to market forces. It would place medicine on the same level as those services regulated by the Services Directive 2006.[174] However, for parties like UEMS and CPME, this is no justification to allow aesthetic surgery to escape the traditional methods of medical standardisation. This is because treatments will still be provided by medical doctors who should be bound by professional and ethical obligations.[175] Professionalisation requires that doctors operating on a market should not abandon their professional hat and simply change it for a business hat. The fact that reatments might be subject to market forces is not sufficient to allow them to use European standardisation.

The nature of the European standardisation process facilitates de-professionalisation – not only because of the lack of scientific evidence, but also because all interested parties can freely participate. This has resulted in a difficult paradox in the European standardisation process for Aesthetic Surgery Services. The process has been started to regulate the competence of medical

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[172] J van Everdingen et al. (eds.), above n 160, 210-219.
[173] See A Samanta et al., 'The Role of Clinical Guidelines in Medical Negligence Litigation: A Shift from the Bolam Standard?' (2006) 14 *Medical Law Review* 321.
[174] Interview with UEMS and CPME (Warsaw) on 19 February 2013. See also H Willensky, above n 171.
[175] Interview with UEMS and CPME (Warsaw) on 19 February 2013. See also E Freidson, above n 155, 305-308.

professionals on the market and to increase transparency in a market where many providers with different qualifications are operating. The Chairman of the Dutch mirror committee for Aesthetic Surgery Services described this situation as a market with "good guys and bad guys".[176] Traditional medical standardisation has been unable to deal with this situation.[177] As a consequence, it is legitimate to escape these structures of medical standardisation to attempt to find a solution through external mechanisms such as CEN. This has to be done in order to protect the integrity of the medical profession itself. In order to do this, they have to surrender part of their professionalisation by sitting around the table with practitioners who are acting as pure market players and who are also able to participate in the European standardisation process. Sometimes these practitioners are not even medical professionals – they often do not have the necessary qualifications to do what they are doing and they do not feel bound by professional or ethical obligations. In order to reach agreement with these practitioners, the more traditional medical professionals have to abandon some of their own professionalisation. At the same time, the dialogue with the market players is used to attempt to impose a process of professionalisation on them. That could again be considered as an ultimate indication of professionalism. It would mean that "the bad guys" would no longer be able to perform certain treatments, or at least that the standard would reject the possibility of these treatments being performed by them. This professional starting point will always result in a compromise, but at least the underlying intention has been to approach professionalisation as closely as possible.

C. The role of public authorities and the protection of national legislation in European standardisation

Another important aspect of European standardisation in the healthcare sector is to what extent public authorities play a role in it, and to what extent European standardisation is regarded as a threat to national regulatory frameworks for medical standardisation, which are under strict public control in a number of Member States. It has already been noted that these national regulatory frameworks are starting to open up to the market, which also means that European standardisation through CEN could become a more realistic possibility. Public authorities have to respond to this. The role of public authorities in the standardisation process for Aesthetic Surgery Services is important. In particular, the French position was very much based on the protection of national legislation.[178] The position of national public authorities was even more

[176] Interview with Chairman of Dutch Mirror Committee for Aesthetic Surgery Services (Goes) on 29 December 2012.
[177] Ibid.
[178] Ibid.

obvious in the Cleft Lip Surgery process. Here, the French Ministry of Health directly intervened to object to the standardisation process.[179] This position has been made more explicit in some of the comments that were made when the national standardisation organisations voted on the proposal for a Cleft Lip Surgery standard. In particular, the French position should be noted:

"Such a topic is considered as a very sensitive one linked to the patient safety. This is why in France the management of cleft lip and palate falls within the remit of the public authorities in charge of the health system, organised by dedicated regulations. Moreover, the production of recommendations for good practices that contribute to the continuous improvement of quality and safety of care is in the competence of an administrative and independent scientific authority (the Haute Autorité de Santé)"[180]

This comment illustrates a "competence justification" used by Member States to refuse to engage with European standardisation. There is no engagement with the substantive provisions of the proposed European standard. The simple existence of national regulatory competence is sufficient to reject the possibility of European standardisation. In this particular example, the invoked clash is also framed as a clash between private regulation and public legislation. In that respect, it is important that France has in a way "publicised" traditional medical standardisation by creating an authority and a public regulatory framework through which medical standards are made.

In France, the Haute Autorité de Santé ("HAS") is responsible for the supervision of the quality of healthcare services.[181] Although it is not strictly speaking a Government body, it is a public body on which the French State exercises significant influence. The French State appoints delegates to the Board of HAS. The majority of the budget of HAS comes from licence fees for the advertising of medication, grants from health insurers and from the French State. HAS is responsible for the supervision and certification of hospitals, individual doctors and for the development of scientific healthcare standards. These standards are developed within the organisational structure of HAS. The initiative for a standard can be taken by the Ministry of Health, scientific organisations or HAS itself. HAS can decide to outsource the making of a particular standard, but it will always remain fully responsible for the final instrument. Medical doctors are brought within the organisation to work in committees within HAS to develop standards. They will usually be joined by public officials and health economists. As a result, it can

[179] Interview with ECO (Skype) on 14 March 2012.
[180] Voting Results: *"Creation of a new CEN Project Committee on 'Healthcare services for cleft lip and/or palate'"*, CENBT/8561, Brussels, April 2011.
[181] Haute Autorité de Sante: http://www.has-sante.fr/portail/jcms/c_1002212/fr/missions-de-la-has.

reasonably be concluded that the medical profession has surrendered at least some of its autonomy. At the same time, it should be noted that the medical profession has never been completely autonomous vis-à-vis the State and that the medical aspects of the standardisation process are likely to remain within the exclusive control of the medical profession.

The French comments provide evidence that the French State is able to impose its views on AFNOR, the French standardisation organisation. In an indirect way, this has an impact at the European level. It shows that an initiative for European regulation of a private nature does not take away the competence of the State to control regulation in the healthcare sector. If the cooperation between public and private parties in medical standardisation at the national level is hierarchical, this hierarchy will effectively be transplanted to the European level. This might be specific for the regulation of healthcare services, for which the State is still assuming the main responsibility at the national level. However, the French and Spanish reactions clearly show that if the regulation of a particular service is still vertically, or hierarchically, controlled by the State at the national level, this position can also be enforced at the European level. Essentially, what this means is that the CEN standardisation process is not sufficiently transnational to take matters out of the control of the State. The State is able to "infiltrate" in the standardisation process and protect the hierarchical nature of national regulation. This is not the same for all Member States. For example, in the UK and in the Netherlands, the State, public bodies or agencies do not have the same influence on the national standardisation organisations.[182]

D. European healthcare standards vis-à-vis national healthcare standards

Finally, a common objection to European standardisation in the healthcare sector is the argument that European standards would be unnecessary or undesirable because there are already sufficient and adequate national standards. With the Cleft Lip Surgery proposal, some Member States took the position that there was no need for a European standard, since they already had national standards that were perfectly capable of guaranteeing good quality healthcare.[183] The creation of European standards would be a risk to these national standards, as it could result in the lowest common denominator. If there are Member States which feel a need for higher medical standards, these Member States would be happy to share their national standards with them. This position has been taken by Germany and the Netherlands.

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[182] Interview with NEN (Delft) on 12 April 2012 and Interview with Chairman of Dutch Mirror Committee for Aesthetic Surgery Services (Goes) on 29 December 2012.

[183] Voting Results: *"Creation of a new CEN Project Committee on 'Healthcare services for cleft lip and/or palate'"*, CENBT/8561, Brussels, April 2011.

The comments of the Netherlands were very clear:

"European standardization of healthcare services across Europe is unrealistic. Healthcare services for cleft lip and or palate in the Netherlands is aiming for optimal healthcare. Optimal healthcare might not be realistic (financially) for all individual countries. European standardization would most likely aim for an average level of healthcare. It is not of the interest of the Netherlands neither to develop nor to contribute to such a standard"[184]

This statement clearly expresses the fear that European standards would result in a lowering of national standards. A response to this objection could be that a European minimum standard would not mean that a higher national standard could no longer be used. The European standard would only provide the required minimum level of care. However, it would then be useless for Dutch stakeholders to participate and to contribute financially to the standardisation process. Moreover, the objection was based on a fear that public authorities, or health insurers, would use European standards to make them legally binding in their contact with healthcare providers.[185] A lower European standard would mean a reduction in costs. The use of European standards would then result in a lower level of care than the level of care provided on the basis of national standards. This would not be in the best interests of patients. An additional complication is that in many Member States there are not even national medical standards for certain treatments. For example, although the Netherlands has managed to adopt a national standard for certain aspects of cleft care, most care is still provided on the basis of regional protocols.[186] Europeanisation of such standards would be in conflict with the principle of subsidiarity in healthcare and would threaten the individual or local nature of healthcare provision.

V. A PRELIMINARY CONCLUSION

The first section of this chapter showed that the European regulatory framework for healthcare services provides scope for European standardisation. In particular, the emphasis on information requirements in the Cross-Border Healthcare Directive means that European standardisation could regulate aspects of the doctor-patient relationship at the national level. However, this European regulatory framework does not necessarily match with national regulatory frameworks. It defers to national standards for medical treatment. With the various national differences in how these standards are made, it is unlikely that a European standard would play a uniform role

[184] Ibid.
[185] Interview with NEN (Delft) on 12 April 2012.
[186] Ibid.

in the regulation of healthcare services at the national level. This is primarily because the extent to which private regulation is allowed to play a role in the regulation of healthcare services is widely divergent across the EU. This is not something European standardisation could necessarily have an impact on. On the contrary, national cultures of standardisation could act as obstacles to European standardisation. This would be purely on the level of the standard-making, and not necessarily on the level of their application. It would not necessarily mean that European healthcare standards would not be applied in private law. However, the public law dominance in the making of healthcare standards is also likely to have a negative impact on the use of the standards in private law, because it limits their scope of application. Finally, the fact that there is limited scope for private regulation of healthcare services at the national level will result in very few private European standards being adopted. This is because Member States are likely to defend and reinforce their public dominance in medical standardisation at the European level.

Overall, two main problems with European standardisation of healthcare services can be identified. First of all, the European standardisation process is incompatible with evidence-based medical standardisation. Although it might be possible to incorporate elements of evidence-based standardisation in the process, the standardisation process through CEN is significantly more political than traditional medical standardisation. Decisions are taken on the basis of consensus among the various European participants. There is no guarantee in the process that this consensus reflects medical scientific evidence. Participants in European standardisation would argue that they are working on a different, and additional, type of healthcare standards. However, this argument is not accepted by a majority of the medical profession. Moreover, there is a fear that European standardisation is used by outsiders – or even medical professionals themselves – as a justification to cut on funding, or as a tool to protect and restrict the market for certain treatments. In addition, European standardisation could become an escape route to doctors or to pseudo-medical professions to provide a sense of public legitimacy to what they are doing. Whether or not this strong criticism of European standardisation by the medical profession is justified does not really matter. What matters is that it is a genuine concern which means that the medical profession is strongly opposed to European standardisation. Without the support of the medical profession and the various European medical associations, it is unlikely that European standardisation will become more prominent in the healthcare sector.

Secondly, European standardisation faces strong opposition from public authorities in the Member States. This is particularly true for those Member States in which public authorities are in strict control of medical standardisation. This hierarchical relationship between public and private regulation is subsequently protected at the European level. The result is that these Member States are likely to vote against European standardisation projects in the healthcare sector. Moreover, if a project is started, they will send representatives of the public authorities whose primary purpose is to protect national legislation. As a result, the participation of these Member States is not constructive. Moreover, there is a serious concern in the old Member States that any standards which are adopted through European standardisation will be lower than existing national standards. This is again a reason to refuse to engage with European standardisation of healthcare services. Although the European standard would not obtain binding force after its adoption, it would be useless for Member States and for stakeholders to participate in the creation of a standard that would be lower than their existing standard. The Cleft Lip Surgery proposal shows that European standardisation is not accepted as a tool for development aid for the new Member States. One of the reasons is that the funding of European standardisation has to come from the stakeholders themselves.

In conclusion, there are a number of serious obstacles to European standardisation of healthcare services. They are also reflected in today's reality – very few standards have been adopted, those standards that are in the process of being made face strong opposition both at the national and at the European level, and there are no indications that European standardisation is likely to become more prominent in the healthcare sector in the future. On that basis, it can be concluded that European standardisation of healthcare services remains both controversial and marginal.